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Atty. Dkt. No. 034827-1501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Huang, et al.

Title: METHODS AND
COMPOSITIONS FOR THE
AMPLIFICATION OF
MUTATIONS IN THE
DIAGNOSIS OF CYSTIC
FIBROSIS

Appl. No.: 10/659,582

Filing Date: 09/09/2003

Examiner: Unknown

Art Unit: Unknown

CERTIFICATE OF MAILING
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INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003.

Accordingly, copies of these types of documents are not being supplied in connection with this

application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check

being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date June 10, 2004

By Barry Wilson

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JUN 14 2004

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

2

Complete if Known

Application Number	10/659,582
Filing Date	09/09/2003
First Named Inventor	Dong Hui Huang
Group Art Unit	1637
Examiner Name	Unknown

Attorney Docket Number 034827-1501

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
A1	4,582,788			Erlich	04-15-1986	
A2	4,683,194			Saiki et al.	07-28-1987	
A3	4,683,202			Mullis	07-28-1987	
A4	4,998,617			Ladd et al.	03-12-1991	
A5	5,130,238			Malek et al.	07-14-1992	
A6	5,169,766			Schuster et al.	12-08-1992	
A7	5,846,710			Bajaj	12-08-1998	
A8	5,885,775			Haff et al.	03-23-1999	
A9	5,888,819			Goelet et al.	03-30-1999	
A10	5,955,377			Maul et al.	09-21-1999	
A11	5,981,178			Tsui et al.	11-09-1999	
A12	6,011,588			Kim	01-04-2000	
A13	6,288,220			Kambara et al.	09-11-2001	
A14	6,355,429			Nygren et al.	03-12-2002	
A15	6,403,320			Read et al.	06-11-2002	
A16	6,406,844			Pirring et al.	06-18-2002	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
A17	WO	88/10315			Siska Diagnostics, Inc.	12-29-1988		
A18	WO	89/06700			Genentech, Inc.	07-27-1989		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ⁶
	A19	Flanigan et al. "Rapid direct sequence analysis of the dystrophin gene." Am J Hum Genet. 2003 Apr;72(4):931-9.					

Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/659,582
				Filing Date	09/09/2003
				First Named Inventor	Dong Hui Huang
				Group Art Unit	1637
				Examiner Name	Unknown
(use as many sheets as necessary)				Attorney Docket Number	034827-1501
Sheet	2	of	2		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	A20	Hoogendoorn, B. et al., "Genotyping Single Nucleotide Polymorphism by Primer Extension and High Performance Liquid Chromatography" Human Genetics (1999) 104:89-93		T ⁶
	A21	Jenison et al., Use of a thin film biosensor for rapid visual detection of PCR products in a multiplex format." Biosens Bioelectron. 16(9-12):757-63 (2001)		
	A22	Kwoh, D. et al., Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format." Proc. Natl. Acad. Sci. (U.S.A.) 86:1173 (1989)		
	A23	Landegren, U. et al. "A ligase-mediated gene detection technique." (1988) Science 241:1077-1080		
	A24	Mullis, K. et al., "Specific enzymatic amplification of DNA in Vitro: The Polymerase chain reaction." Cold Spring Harbor Symp. Quant. Biol. 51:263-273 (1986)		
	A25	Nickerson et al., "Automated DNA diagnostics using an ELISA-based oligonucleotide ligation assay." (1990) Proc. Natl. Acad. Sci. U.S.A. 87:8923-8927		
	A26	Piggee, C. et al. "Capillary Electrophoresis for the Detection of Known Point Mutations by Single-Nucleotide Primer Extension and Laser-Induced Fluorescence Detection" Journal of Chromatography A 781 (1997), p. 367-375		
	A27	Poddar "Symmetric vs asymmetric PCR and molecular beacon probe in the detection of a target gene of adenovirus." Molec. And Cell. Probes 14:25-32 (2000)		
	A28	Walker, G. T. et al., "Isothermal in vitro amplification of DNA by a restriction enzyme/DNA polymerase system." Proc. Natl. Acad. Sci. (U.S.A.) 89:392-396 (1992)		
	A29	Wall et al. "A 31-mutation assay for cystic fibrosis testing in the clinical molecular diagnostics laboratory." Human Mutation 5:333-338, 1995.		

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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